K021328

JUN 26 2003

SAFETY AND EFFECTIVNESS STATEMENT.

TRADE NAME: SMART BAG® MO

COMMON NAME: BAG-VALVE-MASK RESUSCITATOR

REGULATORY CLASS: II

510K # :

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED:

DMR Plus Disposable Manual Resuscitator - 510K #: K973419

DESCRIPTION OF THE DEVICE:

The SMART BAG® MO is a manual resuscitator comprising a self inflating bag, a one way valve and a facemask designed to supply ventilations to a non-breathing patient by the compression of the bag portion of the device by the operator.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Similar in all respects to the predicate device, 510(k) #: K973419, this product has the addition of a flow-limiting valve that is responsive to the squeeze of the balloon applied by the rescuer. In cases where high flowrates are required to overcome mask leakage or adverse patient conditions, the Manual Override Control is provided to disable the flow controlling mechanism and allow the SMART BAG ®MO to act like a standard BVM.

ASSESSMENT OF PERFORMANCE DATA

The submission incorporated a significant amount of non-clinical test data to support the claim of substantial equivalence. This test data reviewed the performance of the device against both the current domestic and international standards for these devices.

In particular, references were made to ISO 8382-1988.

CONCLUSIONS BASED ON PERFORMANCE DATA

The testing undertaken verified that the SMART BAG® MO device, when compared with the performance of the device to which substantial equivalence is claimed, performed within specification.

CONTACT PERSON: KEVIN BOWDEN,
DIRECTOR OF PRODUCT TECHNOLOGY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2003

Mr. Kevin Bowdon
Director of Product Technology
O-Two Systems International Incorporated
7575 Kimbel Street
Mississauga, Ontario
CANADA L5S 1C8

Re: K021328
Trade/Device Name: SMART BAG® ***MO***
Regulation Number: 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: II
Product Code: BTM
Dated: May 14, 2003
Received: May 16, 2003

Dear Mr. Bowden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510K Number (if known): K021328

Device Name: SMART BAG®*MO*

Indications for Use:

"The SMART BAG®*MO* is intended for manual ventilation of patients using ambient air or supplemental oxygen supplied from an oxygen source. The SMART BAG®*MO* is available in a child and an adult size. The SMART BAG®*MO* is available with components that can be autoclaved, or can be chemically disinfected. A single use disposable version is also available. The SMART BAG®*MO* includes a flow limiting valve that limits the inspiratory flow to approximately 40 litres per minute, for the adult version and 30 litres per minute for the child version. The flow limiting valve is intended to minimize gastric inflation during manual ventilation. The flow limiting valve can be disabled to permit conventional operation of the resuscitator".

Kevin Bowden,
Director of Product Technology
O-Two Systems International Inc.

January 20th 2003

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K021328